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Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

JUN - 9 2008

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: CONNEXX Locking Tibia Nail

COMMON NAME: Intramedullary Nail System

CLASSIFICATION: Single/multiple component metallic bone fixation appliances and accessories (see 21 CFR, Sec. 888.3040)

Rod, Fixation, Intramedullary and Accessories
(see 21 CFR, Sec. 888.3020)

DEVICE PRODUCT CODE: HWC

SUBSEQUENT PRODUCT CODE: HSB

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes Tibial Nail System **(K040762)**
DePuy/ACE VersaNail Tibial Nail **(K032097)**
Synthes Cannulated Tibial Nail **(K962047)**
Synthes Universal Tibial Nail & Unreamed Tibial Nail **(K914453)**
BioPro Wujin #3 Tibial Nail **(K002325)**
Zimmer Sirus Intramedullary Nail-Femoral and Tibial Nail **(K043270)**
Stryker Interlocking Tibial Nailing System **(K915435)**

DEVICE DESCRIPTION:

The I.T.S. CONNEXX Locking Tibia Nail is a fracture fixation intramedullary rod with locking/nonlocking cross-screw fixation for repairing long bone tibia fractures of a patient. The I.T.S. CONNEXX Locking Tibia Nail System is composed of a cannulated 9mm and 10mm diameter nail in various lengths (255mm to 420mm in 15mm increments) and two styles of cross-screw attachments, a 4.7mm standard cortical screw as a non-locking feature and a 4.7mm Bolt Double Thread as a non-locking feature (two thread diameters on the screw for thread engagement into the proximal and distal cortex of the tibial shaft when inserted). A cannulated 'locking key sleeve' and 'end cap' combination function to firmly fix the above two cross-screw attachments to the 9mm or 10mm nail for 'locking' the cross-screws to the tibia nail – thus making the entire IM rod/cross-screw assembly 'angle-stable locking'. All tibial rods and cross-screws are composed of high strength 6-4 ELI Titanium Alloy to ASTM F-136. A full compliment of instrumentation is available for use with the system.

Proper alignment instrumentation is incorporated for proper postioning of the locking screw to screw hole in the IM rod -- along with the assistance of X-ray Fluoroscopy.

INTENDED USE:

The ***intended use*** of the I.T.S. CONNEXX Locking Tibia Nail is to stabilize fractures of the proximal and distal tibia and the tibial shaft in a pediatric or adult patient.

Indications for use include open and closed tibial shaft fractures; certain pre and post-isthmic fractures, tibial malunions and non-unions, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, metaphyseal and epiphyseal fractures, transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, bone support, and fractures with bone loss.

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. CONNEXX Locking Tibia Nail is substantially equivalent to the Synthes, DePuy/ACE, Zimmer, Stryker, and Biopro IM Tibia Nail systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. CONNEXX Locking Tibia Nail is shown to be safe and effective for use in fracture fixation of the tibia.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2008

I.T.S. Implantat-Technologie-Systeme GmbH
% Engineering Consulting Services, Inc.
Mr. Al Lippincott
3150 E. 200th Street
Prior Lake, Minnesota 55372

Re: K080706
Trade/Device Name: CONNEXX Locking Tibia Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB, JDS, HWC
Dated: March 10, 2008
Received: March 12, 2008

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: K080706

DEVICE NAME: **CONNEXX Locking Tibia Nail**

INDICATIONS FOR USE:

Indications for use include open and closed tibial shaft fractures; certain pre and post-isthmic fractures, tibial malunions and non-unions, corrective osteotomies, pathologic fractures, pseudoarthrothis of the tibial shaft, mataphyseal and epiphyseal fractures, transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, bone transport, and fractures with bone loss.

Prescription Use Yes AND/OR Over-The-Counter-Use No

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080706